

**REMARKS**

Claims 1-12, 17, 19-22, and 25-36 are pending in the application. Claims 5, 7-10, 17, 19-22, 29 and 31-34 are withdrawn from consideration based on applicants' response to the restriction requirement. Claims 13-16, 18, 23 and 24 are canceled. Claims 1-4, 6, 11, 12, 25-28, 30, 35 and 36 are rejected.

**Claim Objections**

In paragraph 2 at page 2 of the Office Action, the Examiner objected to claims 11, 12, 23, 24, 35 and 36 as being in improper multiple dependent form.

Each of the still pending claims objected to by the Examiner has been amended so that it no longer depends from other claims which are multiply dependent.

**Claim Rejections - 35 U.S.C. § 101**

In paragraph 3 at page 2 of the Office Action, the Examiner rejected claims 13-16, 18, 23 and 24 under 35 U.S.C. § 101 because "use" claims are not acceptable under U.S. practice.

The rejected "use" claims have been canceled.

**Claim Rejections - 35 U.S.C. § 112**

A. In paragraph 4 at page 3 of the Office Action, the Examiner rejected claims 1, 3, 6, 11-13, 15, 18, 23-25, 27, 30, 35 and 36 under 35 U.S.C. § 112, second paragraph, as being vague and indefinite because allegedly it is unclear what is meant by the phrase "the biological activity of galectin-3."

Independent claims 1 and 25 have been amended to include the recitations of non-rejected claims 2 and 26, that the biological activity is to promote the production of extracellular matrix from extracellular matrix-producing cells.

**B.** In paragraph 5 at page 3 of the Office Action, the Examiner rejected use claims 13-16, 18, 23 and 24 as allegedly being indefinite, because they do not set forth specific process steps.

Claims 13-16, 18, 23 and 24 have been canceled.

**C.** In paragraph 6 at page 3 of the Office Action, the Examiner rejected method claims 25-28, 30, 35 and 36 as allegedly being indefinite because they lack essential steps in the method for inhibiting the overproduction and the accumulation of extracellular matrix. In particular, the Examiner stated that the claims should include the method of administration, the effective amount, and the outcome of the treatment.

From the specification, it is clear that the method of administration is not particularly limited. Accordingly, the method of administration need not be included in the claims. Breadth is not indefiniteness.

Independent claim 25 has been amended to recite the effective amount of the compound used.

Further, in order to expedite prosecution, claim 25 has been amended to additionally recite the outcome of the treatment.

#### **Claim Rejections - 35 U.S.C. § 102**

In paragraph 7 at page 4 of the Office Action, the Examiner rejected pharmaceutical composition claims 1-2, 4, 6, 13 and 18 under 35 U.S.C. § 102 as being anticipated by *Dong et al.* (FEBS Letters 395, 165-169 (1996)).

Amendment Under 37 C.F.R. § 1.111  
U.S. Serial No. 09/744,328

The Examiner's position was that *Dong et al.* teach a biological activity of galectin-3 and that the response can be completely blocked with a compound that is an inhibitor of galectin-3 binding (e.g., a sugar).

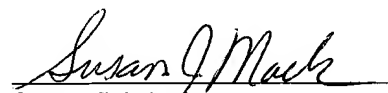
This rejection has been overcome by amending claim 1 to include the recitation of non-rejected claim 3.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: October 15, 2002

**APPENDIX**  
**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

**Claims 13-16, 18, 23 and 24 are canceled.**

**The claims are amended as follows:**

**Claim 1 (Amended)** A pharmaceutical composition having an inhibitory effect on glomerular nephritis, diabetic nephropathy or tissue fibrosis caused by the overproduction and the accumulation of extracellular matrix, said composition comprising as an active ingredient an effective amount of a compound that promotes the production of extracellular matrix from an extracellular matrix-producing cell~~having an inhibitory effect on the biological activity of~~ galectin-3.

**Claim 3 (Amended)** The pharmaceutical composition according to claim 1, which exhibits an inhibitory effect on glomerular nephritis, diabetic nephropathy or tissue fibrosis ~~of which cause is~~caused by the overproduction and the accumulation of extracellular matrix.

**Claim 11 (Amended)** The pharmaceutical composition according to any ~~one of~~ claims 1 to ~~104~~, which is a therapeutic or preventive agent.

**Claim 12 (Amended)** The pharmaceutical composition according to ~~any of~~ claims ~~3 to 11~~, wherein the glomerular nephritis, diabetic nephropathy or tissue fibrosis is glomerular nephritis, diabetic nephropathy or tissue fibrosis, respectively, caused by the abnormal proliferation of mesangium cells.

**Claim 25 (Amended)** A method for inhibition of glomerular nephritis, diabetic nephropathy or tissue fibrosis caused by the overproduction and the accumulation of

extracellular matrix, said method comprising ~~administering~~administering an effective amount of  
a compound having an inhibitory effect on the biological activity of galectin-3, to a subject  
which needs said inhibition, to thereby inhibit the overproduction and accumulation of  
extracellular matrix.

**Claim 27** (Amended) The method ~~composition~~ according to claim 25, for  
inhibition of glomerular nephritis, diabetic nephropathy or tissue fibrosis ~~of which caused by~~ is  
the overproduction and the accumulation of extracellular matrix.

**Claim 28** (Amended) The method according to claim 27, wherein the biological  
activity of galectin-3 is to promote the production of extracellular matrix from an extracellular  
matrix-producing cell.

**Claim 35** (Amended) The method according to any ~~one~~ of claims 25 to ~~34~~28,  
which is for ~~the~~ therapeutic or preventive treatment.

**Claim 36** (Amended) The method according to ~~any of~~ claims 27 to ~~35~~or 28,  
wherein the glomerular nephritis, diabetic nephropathy or tissue fibrosis is glomerular nephritis,  
diabetic nephropathy or tissue fibrosis, respectively, caused by the abnormal proliferation of  
mesangium cells.